

REMARKS

Claims 1 - 3, 5 - 12 and 21 - 28 are in this application and are presented for consideration. By this Amendment Applicant has canceled 9 claims and has presented 8 new claims such that no additional fee is required as to the total number of claims. Further of the claims canceled, two were independent and Applicant now submits three new independent claims such that the fee for one new independent claim is attached.

The Amendment makes changes to several claims to improve the form and to clarify an important aspect of the combination according to Applicant's invention. Further, new independent claims 23 and 25 have been added which highlight important aspects of the combination according to the two preferred embodiments (the embodiment of Figs. 3 and 5 respectively). New claim 27 highlights the combination based on the set of containers with the particulars of the containers as specified.

The specification has been objected to as not including an abstract.

Applicant notes that the application is a PCT National Phase Application such that it necessarily includes an English language abstract (there is no requirement for Applicant to provide a translation of the abstract). Applicant presents a new abstract attached to this response.

The claims have been objected to based on informalities. Applicant has revised claims paying close attention to the Examiner's comments. Applicant wishes to thank the Examiner for the careful reading of the claims and for the helpful comments. It is Applicant's position that all issues have been addressed. With regard to the "bullet points" Applicant has simply

removed these. Should the Examiner determine that steps should include letter designations, these can be added.

Claims 1 - 3, 5, 6, 8 - 13 and 17 have been rejected as being anticipated by Chaffin, III et al. (U.S. 831,006, cited by the Applicant). Applicant has referred to this reference below as "Chaffin".

The invention provides a novel combination of method steps and system elements based on the plurality of containers being provided with each container having a unique identification code associated with it and the container having a marking including the unique identification code wherein this code is associated with the container and the marking is applied to the container during the production of or packaging of the container. Specifically, essentially from the containers first time of real existence (as it is being moved from its location of production or packaging or when it is being moved from its point of completion) the container has a unique identity which is indicated via a marking or the like. Applicant has used the term marking to include an element with indicia or the like (particularly for optical reading) but it should not be limited to this per se and includes inter alia means for passing the code from the container to some structure for reading the code (this could be but is not limited to optical means, magnetic sensing, radio frequency identification tag type structures and ultrasonic identification tag structures). Because there is a marking at the time of production there is a uniqueness as to identification of each container relative to each possible other container. This is used in the system and method in combination with a patient identification to greatly rule out many problems which have been encountered in the analytical laboratory field.

The Chaffin reference teaches containers which receive an identification number only when it is actually used. With this arrangement numerous identical containers are on hand and the user generates several sets of random numbers x, y, z, etc.. It must be appreciated that in the example disclosed by Chaffin the content of each probe or container which receives a y identification number is divided in to two or more sub-samples and each sub-sample is placed in a container of a set of sub-containers. Each sub-container then receives a z identification number from a further set of identification numbers. The y containers may be called "mother" tubes and the z tubes may be called "daughter tubes" (as pointed out at page 10, line 11 of Chaffin). The process as described could be repeated more than once in series such that each daughter tube originates several further daughter tubes. A separate set of random numbers must be available for each mother-daughter "relation" process. This reduces the total available numbers.

Each container or tube of Chaffin receives a code which is not fully unique. Such a code may be different from other codes for that specific laboratory or hospital for a limited period of time. If two different hospitals or laboratories use the same system, they cannot exchange probes or containers for performing different analyses. The reason for this is that the two structures might well generate for different patients the same y and z identification code. Different numbers are generated from the random number sets only within the same hospital/laboratory or other facility.

Printing and applying labels when they have to be used is another requirement of the system disclosed by Chaffin. This is a costly and inefficient operation. It is also one of the most relevant sources of mistakes, since labels could be misplaced or misapplied.

A server or host computer must be provided, which includes a memory 13 and a logic 32. It should be noted that (contrary to what is stated in several parts of the office action), the memory 13 and the logic 32 are parts of the very same computer and not different and separate units. The host computer receives on its memory 13 directly the combined data x/y; y/z; z/Test-Results from the various stations in the laboratory or hospital. This requires a common storage memory to which all the apparatus in the network are interfaced. The host computer must be programmed to perform the required operations on the data which arrive with the specific structure as defined in the specification of Chaffin. The system, therefore, can only be introduced in a hospital or a laboratory by completely re-programming the information system.

Usually, in the state-of-the-art systems the host computer is programmed to receive a combination of patient codes and test results. In other words, the host computer is programmed to receive the test results already combined to the patient data.

The Chaffin system requires that the host computer be:

- a) provided with a storage memory interfaced with all the devices of the laboratory or hospital;
- b) programmed to receive in said memory very specific sets of data (x/y - y/z - z/test results) and only if it receives such a structured string of data is it able to combine the test results with the patient data.

The system disclosed by Chaffin, therefore, could not be implemented in a usual data processing system of an existing laboratory without completely changing and reprogramming it.

According to the invention as claimed, containers or test tubes or similar structures are pre-labeled at the production stage (see the independent claims). This provides significant advantages including:

- 1) Labeling at the time of use is not required, and this reduces errors. Other advantages in terms of safety, cost saving and easy of operation are discussed in the specification;
- 2) The number of each container or tube is unique and test tubes containing samples of different patients can be exchanged among different laboratories without any risk of confusion or mistakes;
- 3) The number assigned to each test tube or container may include data concerning its use (different test tubes are provided for different tests) or data for quality control, such as the expiration date (see e.g. claim 16). This can provide additional advantages, since if a wrong test tube is used in an analyzer, the analyzer can recognize the mistake thanks to the code printed on the test tube.

Accordingly, Chaffin fails to teach and fails to suggest the combination of features as presented for example in method claim 1 and system claim 10 (the amended independent claims). Further, the reference clearly fails to suggest the combination of new claims 23 and 25, which detail a series of method steps which are clearly not suggested and clearly not taught by Chaffin. Accordingly favorable consideration of these claims and claims depending thereon is requested.

Claims 4, 7, 14, 15, 18 and 19 have been rejected as being obvious based on the teachings of Chaffin in view of Knepple et al..

Knepple teaches the possibility of providing pre-numbered test tubes. However, the references together fail to teach and fail to suggest the combination of features as claimed. The use of such test tubes in a system as per Chaffin is not suggested. Such a use would require a complete redesign of the Chaffin system. Chaffin is based on the idea of using separate random number sets from which random numbers (x, y, z, etc.) for each patient and test tubes are generated and combined to the test results. The host computer is programmed to process these randomly generated numbers in a specific way.

The proposed combination would require a removal of the random number sets and relevant processing as proposed by Chaffin and would instead require an introduction in the system of pre-labeled test tubes with a resulting complete change in the basic system taught by Chaffin. There is no teaching and no suggestion which would motivate the person of ordinary skill in the art to provide such a redesign. The references do not direct the person of ordinary skill in the art toward the combination claimed.

The method of claim 23 presents a combination which is further distinguished from the teachings of Chaffin and Knepple. According to this method a common data processing system of the laboratory or hospital can be used to implement the system and method. Such systems which are used in laboratories and hospitals use a host computer which receives patient information code data from the various devices along with the test results. With this, for example, each analyzer sends back to the host computer the test result which is already combined with the patient identification code. This has significant advantages over the prior art as a whole including any combination suggested by the teachings of Chaffin and Knepple.

According to the method of Figs. 1 and 3 and as highlighted in method claims 1, system claim 10 and new independent claim 23 the system and method of the invention can be implemented using known and established processing systems based on the host computer receiving as input data the combination of patient identification code and test result. This allows a laboratory or hospital to establish a mix system, i.e. a system where some of the test tubes or containers are handled and managed according to known processes while other containers are managed and handled according to the system and method of the invention. There is no need for an extensive reprogramming of the computer network (this is highlighted in the specification in more detail). Certainly the prior art including Chaffin and Knepple fail to teach and fail to suggest the combination of method claim 23.

New claim 25 highlights the combination of method steps wherein the host computer is reprogrammed in order to receive the test results and the tube identification code from the analyzing device and to provide a linking or combination of the test results to the patient identification code. Such a combination or linking is made possible by the fact that at one stage (via unit 17 according to the embodiment) the patient code CP and the test tubes 13 are read and each test tube identification code CI is combined with the patient identification code CP (or an association table is formed) such that the combination is stored in the host computer (or the association table is stored). Certainly the subject matter of new claim 25 defines over Chaffin or the combination of prior art including Chaffin and Knepple.

The invention as claimed differs from Chaffin in substantial ways. There is no generation of random numbers. Several test tubes are provided each having their own identification code CI associated to the patient identification code CP (CI-CP combination or association). Simultaneously or afterwards the containers are filled with biological samples

and sent to the analyzers. The analyzer then sends to the host computer the test analysis and the identification code of the test tube on which the analysis was performed. The host computer directly combines the test results to the patient data via a CP-CI combination or association.

Claims 16 and 20 have been rejected as being obvious based on Chaffin in view of Carr et al. (U.S. 5,888,825).

Applicant has presented new claim 27 which includes features from claim 16 or 20. New claim 27 highlights a set of containers wherein each container has a container body a marking or label with a unique code applied initially (so the container has this for all stages of use) and the container has a means for determining an expiry date. The prior art including Chaffin and Carr fail to teach and fail to suggest this combination of features. Carr discloses test tubes with a bar code provided after introducing the sample into the test tube. Such a bar code may include data on the expiration date of the sample. This does not suggest the combination as claimed wherein the test tube or container indicates the expiration of the test tube before use. This is particularly useful with regard to test tubes which include reactants or other material which have a limited useful life.

Accordingly Applicant respectfully requests that the Examiner reconsider the rejections in view of the revised claims and in view of the discussion above.

Respectfully submitted  
for Applicant,

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JJM:jj/tf/jms  
70479.10



Enclosed: Request to Charge Deposit Account (for 1 extra independent claim)  
Petition for One Month Extension of Time

DATED: December 12, 2003  
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SHOULD ANY OTHER FEE BE REQUIRED, THE PATENT AND TRADEMARK OFFICE  
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0410.